27 January 2016

Scancell Holdings Plc

Interim Results for the six months ended 31 October 2015

Scancell focuses on the US in a transformational year

Scancell Holdings plc, ('Scancell' or the 'Company') the developer of novel immunotherapies for the treatment of cancer, announces its interim results for the six months ended 31 October 2015.

Highlights:

- Completion of the main study period of the Phase 1/2 clinical trial of SCIB1 ImmunoBody® in patients with Stage III/IV melanoma with continued strong survival data
  - All 20 patients with resected disease remain alive
  - Median observation time in 16 patients who received 2-4mg is now 42 months since study entry and 11 remain disease free
  - Median observation time in four resected patients who received 8mg is 10 months and all remain disease free
  - All nine patients currently on long-term treatment remain disease free up to 39 months from start of SCIB1 treatment
  - Final clinical study report expected in H1 2016

- Continued good progress in development of lead product, Modi-1, from Moditope® platform
  - Improvement in peptide components suggest Modi-1 will be effective in up to 95% of patients with triple negative breast and ovarian cancers
  - Clinical studies anticipated to commence in 2017
  - Important paper outlining the scientific basis for the Moditope® platform published in revered cancer journal, *Cancer Research*

- Loss for the six month period of £1.17 million (2014: loss: £1.34 million)

- Group cash balance at 31 October 2015 was £1.81 million (30 April 2015: £3.06 million)

Post Period Highlights

- Prestigious US scientific team to lead Phase 2 checkpoint inhibitor combination study with SCIB1, expected to commence in 2017

- Results from first pilot study indicate ImmunTraCkeR® has the potential to be used as a companion diagnostic to predict early response to SCIB1. Further studies planned

- John Chiplin appointed Chairman, succeeding David Evans who has stepped down from the role

Richard Goodfellow, Joint CEO of Scancell, said: *"Scancell is in the midst of an exciting transformation. Our focus on the US has resulted in the appointment of Dr Keith Flaherty, one of the world leaders in melanoma clinical research as Principal Investigator for our planned SCIB1/checkpoint inhibitor combination study. The SCIB1 survival data, especially in patients with resected disease is extremely encouraging. All 20 patients with resected Stage III/IV disease remain alive and only 5 have any evidence of disease progression. The strength of the Moditope® platform has been endorsed by the publication of data supporting its scientific basis in Cancer Research, one of the most influential cancer journals in the world. We have strengthened the clinical development team with the appointment of Dr Peter Brown, former Global Head of Oncology at Teva Pharmaceuticals and recently appointed Dr John Chiplin as Chairman, both of whom are US based. We are attracting renewed interest from both investors and pharmaceutical companies on both sides of the Atlantic. Cancer immunotherapy is becoming one of the most important clinical advances of our generation and I have never been more optimistic about the company, its research and the potential for future growth".*

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A full copy of the announcement can be found on the Scancell website: www.scancell.co.uk

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About Scancell

Scancell is developing novel immunotherapies for the treatment of cancer based on its ImmunoBody® and Moditope® technology platforms.

Scancell's first ImmunoBody®, SCIB1 is being developed for the treatment of melanoma and is being evaluated in a Phase 1/2 clinical trial. Data from the trial demonstrate that SCIB1, when used as monotherapy, has a marked effect on tumour load, produces a melanoma-specific immune response and highly encouraging survival trend without serious side effects.

Scancell's ImmunoBody® vaccines target dendritic cells and stimulate both parts of the cellular immune system: the helper cell system where inflammation is stimulated at the tumour site and the cytotoxic T-lymphocyte or CTL response where immune system cells are primed to recognise and kill specific cells.

Pre-clinical data on a combination of SCIB1 and checkpoint inhibition (blockade of the PD-1 immune checkpoint pathway) has shown enhanced tumour destruction and significantly longer survival times than when either treatment was used alone.

Scancell has also identified and patented a series of modified epitopes that stimulate the production of killer CD4+ T cells that destroy tumours without toxicity. The Directors believe that the Moditope® platform could play a major role in the development of safe and effective cancer immunotherapies in the future.

CHAIRMAN'S STATEMENT

I am pleased to report the Company's interim results for the period ended 31 October 2015. During the period the Company has continued to make good progress across all fronts.

- The latest survival and safety data from the Phase 1/2 clinical trial continues to suggest that SCIB1 has the potential to become both the first stand-alone adjuvant treatment for early stage metastatic melanoma and an attractive partner with checkpoint inhibitors for later stage disease.
- Results from a pilot study with ImmunID illustrate ImmunTraCkeR®'s potential to be used as a companion diagnostic to predict early clinical response to SCIB1, both during further clinical trials and during subsequent routine clinical use.
- Scancell is to work with leading US melanoma specialists to conduct a Phase 2 checkpoint inhibitor combination study with SCIB1. This pivotal initiative which aims to demonstrate an increase in the response rates to checkpoint inhibitor therapy without additional toxicity is expected to commence in early 2017.
- The Company's second immunotherapy platform received a significant boost following the publication of a paper in *Cancer Research* underpinning the scientific basis for the Moditope® platform.
- Progress has been made in the pre-clinical development of Modi-1, the lead pipeline candidate from the Moditope® platform significantly increasing the number of patients with triple negative breast and ovarian cancer eligible for treatment.

Financial

Profit and Loss Account
The Group made an overall operating loss for the six month period to 31 October 2015 of £1.37 million (2014: loss of £1.56 million). The reduced loss reflects a fall in research and development expenditure in the period as the SCIB1 clinical trial reaches completion and includes a reduction in administrative expenditure.

Overall the loss for the six month period was £1.17 million (2014: loss £1.34).

Balance Sheet
The cash at bank at 31 October 2015 was £1,813,718 (30 April 2015: £3,059,001) and net assets amounted to £5,606,941 (30 April 2015: £6,754,002).

ImmunoBody® platform

Scancell's ImmunoBody® immunotherapy platform uses the body's immune system to identify, attack and destroy tumours. This is achieved by enhancing the uptake and presentation of cancer antigens to harness high avidity T cell responses. Each ImmunoBody® vaccine can be designed to target a particular cancer in a highly specific manner, offering the potential for enhanced efficacy and safety compared with more conventional approaches. The platform has been validated both in animals and in the clinic with the Company's first cancer vaccine, SCIB1, and many opportunities also exist for the development of a pipeline of ImmunoBody® vaccines, both for cancer and chronic infectious diseases.

SCIB1 melanoma vaccine
In July this year the Company announced that it has closed patient recruitment for its SCIB1 ImmunoBody® Phase 1/2 clinical trial in patients with Stage III/IV melanoma.

The Phase 1/2 clinical trial, conducted across six UK centres, is an open label, non-randomised study to determine the safety and tolerability of SCIB1 administered intramuscularly using an electroporation device (TriGrid Delivery System, manufactured by Ichor Medical Systems, USA). Part 1 was a dose-escalation to determine the dose for Part 2. While the primary objective of the study was to assess safety and tolerability, the study is also assessing immune response, anti-tumour activity and the ability of SCIB1 to delay or prevent disease recurrence in patients with resected disease.

In line with previously reported results, SCIB1 continues to be a safe and well tolerated treatment with no withdrawals from the study due to drug-related adverse events. All 20 patients with resected disease remain alive. The median observation time in the 16 patients with resected disease who received 2-4 mg doses of SCIB1 is now 42 months since study entry and 11 are still disease free. The median observation time for the resected patients on the 8mg dose who were recruited to the study later is 10 months and all are still disease free to date. Patients on long-term continuation treatment will continue to be dosed for up to five years from

the end of the main study period. Nine patients are currently on long-term treatment (up to 11 treatments given) and all remain disease free for periods of up to 39 months from the start of treatment.

The main study closed on 29 October 2015. The Company is in the process of analysing the data and preparing a final clinical study report which is expected to be completed during the first half of 2016.

The enhanced survival and safety in our SCIB1 study combined with the novel mechanism of action which delivers high T cell avidity, has re-ignited the interest of pharmaceutical companies, especially in combination with checkpoint inhibitors.

SCIB2 vaccine
Our second ImmunoBody® vaccine, SCIB2 has been designed to be effective in over 90% of patients that overexpress the cancer antigen NY-ESO-1, including those with lung and other epithelial cancers.

US Clinical Study
The Company has announced the formation of a core US investigator team to lead a checkpoint inhibitor combination study with Scancell's lead cancer vaccine, SCIB1. The team will be led by Principal Investigator Dr Keith Flaherty, Director of the Termeer Center for Targeted Therapy at Massachusetts General Hospital and Associate Professor at Harvard Medical School and will be supported, amongst others yet to be announced, by:

- Dr Paul Chapman (Memorial Sloan Kettering)
- Dr Jennifer Wargo and Dr Michael Davies (MD Anderson)
- Dr Rene Gonzalez (University of Colorado)

The clinical study will assess the impact of adding SCIB1 to checkpoint inhibitors in patients with late stage melanoma. The aim will be to improve the objective response rates of anti-PD-1 ("checkpoint inhibitor") monotherapy without adding additional toxicity. It is expected that the study will enrol approximately 80 Stage III/IV metastatic melanoma patients and commence in early 2017, with completion approximately 18 months later. We are delighted to have secured the help and support of such a prestigious group of US specialists to undertake this important study.

ImmunID Collaboration
The Company is continuing to work with ImmunID on a research project aimed at predicting which patients will respond best to SCIB1 treatment. This collaboration is providing further insight into T cell diversity in patients treated with our SCIB1 vaccine and their response to the treatment over time. Results from the first pilot study with ImmunTraCkeR® have indicated its potential to be used as a companion diagnostic to predict early clinical response to SCIB1 both during further clinical trials with SCIB1 and during routine clinical use; further studies are planned.

Moditope® platform

Modi-1
Scancell's Moditope® immunotherapy platform is based on exploiting the normal immune response to stressed cells, which is largely mediated by CD4+ T cells, and harnessing this mechanism to eradicate cancer cells. Scancell's first target for Moditope® is vimentin – a major cytoskeletal protein found in mesenchymal cells. Many epithelial tumours switch from expression of cytokeratin to vimentin during metastasis in a process known as epithelial mesenchymal transition (EMT); this change in phenotype enables the cell to become mobile and metastasize to new locations in the body.

The pre-clinical development of Modi-1, the lead candidate from our Moditiope® platform technology is continuing to progress and the peptide components have now been modified to include an additional enolase peptide. This improvement has meant that the product is expected to be effective in up to 95% of patients with triple negative breast and ovarian cancers. The Company expects to start clinical trials with Modi-1 in 2017.

The Company was also delighted to announce in January the publication of a paper in *Cancer Research* underpinning the scientific basis for the Moditope® platform. *Cancer Research* is one of the most highly regarded and widely read cancer journals and publication in this prestigious journal is a tribute to Scancell's scientific team under the leadership of Prof Lindy Durrant.

Board

Scancell has strengthened its commercial and clinical development expertise with the appointment of Dr Peter Brown as an advisor to the Company and myself to the Board, initially as a senior Non-Executive Director and now as Chairman. David Evans has stepped down as Chairman and the Board would like to thank him for his exemplary leadership and sage advice during his tenure.

Peter is a highly experienced pre-clinical and clinical development consultant to the pharmaceutical industry and his expertise in designing and managing international late stage oncology clinical trials in both small and large pharmaceutical companies will be of enormous help as the Company continues to grow.

Outlook

The latest data on SCIB1, both in terms of the unprecedented survival of Stage III/IV melanoma patients with resected disease, combined with anti-tumour responses in late stage patients and compelling animal data showing the potential value of a SCIB1/checkpoint inhibitor combination, has set the stage for an expanded clinical trial programme with a prestigious group of US specialists.

Progress has also continued to be made with the Moditope® platform and it is anticipated that the first product, Modi-1, will be moving into the clinic in 2017. Publication of the scientific data supporting the Moditope® platform in *Cancer Research* is also a key milestone and a tribute to the strength of the Company's research team.

These developments have reignited interest in the Company from all of its stakeholders, including the pharmaceutical industry and potential new investors, especially in the US.

The Board believes that investment in further focused clinical studies on both SCIB1 and Moditope® could add significant value to the Company and is exploring with its advisers a number of funding options to ensure that the Company has the resources to progress these programmes further.

As part of this process, the Board and management will be further strengthened to prepare the Company for its future as a later stage development company.

I have become Chairman as the Company is poised for an exciting future and I am committed to strengthening our presence in the US and to building the Company into one of the leaders in immuno-oncology.

John Chiplin
Chairman

Scancell Holdings plc
Consolidated Profit or Loss and Other Comprehensive Income Statement
for the six months to 31 October 2015

	Unaudited Six months 31/10/2015 £	Unaudited Six months 31/10/2014 £	Audited Year to 30/04/2015 £
Continuing operations			
Development expenses	(938,211)	(1,072,984)	(1,998,366)
Administrative expenses	(429,563)	(487,829)	(961,629)
OPERATING LOSS	(1,367,774)	(1,560,813)	(2,959,995)
Interest receivable and similar income	12,011	70,898	131,513
LOSS BEFORE TAXATION	(1,355,763)	(1,489,915)	(2,828,482)
Tax on loss on ordinary activities	180,800	150,000	413,852
LOSS FOR THE PERIOD	**(1,174,963)**	**(1,339,915)**	**(2,414,630)**
Attributable to:			
Equity holders of the parent company	**(1,174,963)**	**(1,339,915)**	**(2,414,630)**
EARNINGS PER ORDINARY SHARE (PENCE) Note 2			
Basic	(0.52)	(0.60)	(1.07)
Diluted	(0.52)	(0.60)	(1.07)

Scancell Holdings plc
Consolidated Statement of Changes in Equity
for the six month period to 31 October 2015

	Share capital	Share premium account	Share option reserve	Retained earnings	Total Equity
	£	£	£	£	£
	Unaudited	*Unaudited*	*Unaudited*	*Unaudited*	*Unaudited*
At 1 May 2015	224,951	16,036,276	613,726	(10,120,951)	6,754,002
(Loss) for the period				(1,174,963)	(1,174,963)
Share option costs			27,902		27,902
At 31 October 2015	224,951	16,036,276	641,628	(11,295,914)	5,606,941
At 1 May 2014	224,951	16,036,276	522,358	(7,706,321)	9,077,264
(Loss) for the period				(1,339,915)	(1,339,915)
Share option costs			46,867		46,867
At 31 October 2014	224,951	16,036,276	569,225	(9,046,236)	7,784,216
	Audited	*Audited*	*Audited*	*Audited*	*Audited*
At 1 May 2014	224,951	16,036,276	522,358	(7,706,321)	9,077,264
(Loss) for the year				(2,414,630)	(2,414,630)
Share option costs			91,368		91,368
At 30 April 2015	224,951	16,036,276	613,726	(10,120,951)	6,754,002

Scancell Holdings plc
Consolidated Statement of Financial Position
as at 31 October 2015

	Unaudited	Unaudited	Audited
	31/10/2015	31/10/2014	30/04/2015
	£	£	£
ASSETS			
Non-current assets			
Plant and equipment	73,250	100,811	86,504
Goodwill	3,415,120	3,415,120	3,415,120
	3,488,370	3,515,931	3,501,624
Current assets			
Trade and other receivables	103,615	78,643	136,785
Income tax assets	590,339	396,652	660,504
Cash and cash equivalents	1,813,718	4,302,052	3,059,001
	2,507,672	4,777,347	3,856,290
TOTAL ASSETS	5,996,042	8,293,278	7,357,914
LIABILITIES			
Current liabilities			
Trade and other payables	(389,101)	(509,062)	(603,912)
TOTAL LIABILITIES	(389,101)	(509,062)	(603,912)
NET CURRENT ASSETS	2,118,571	4,268,285	3,252,378
NET ASSETS	5,606,941	7,784,216	6,754,002
TOTAL EQUITY			
Called up share capital	224,951	224,951	224,951
Share premium account	16,036,276	16,036,276	16,036,276
Share option reserve	641,628	569,225	613,726
Retained earnings	(11,295,914)	(9,046,236)	(10,120,951)
	5,606,941	7,784,216	6,754,002

Scancell Holdings plc
Consolidated Cash Flow Statement
for the six month period to
31 October 2015

	Unaudited Six months 31/10/2015 £	Unaudited Six months 31/10/2014 £	Audited Year to 30/04/2015 £
Cash flows from operating activities			
Operating (loss) for the period	(1,367,775)	(1,560,813)	(2,959,995)
Depreciation	13,254	14,810	29,117
Share based payment expense	27,902	46,867	91,368
Operating (loss) profit for the year before changes in working capital	(1,326,619)	(1,499,136)	(2,839,510)
(Increase)/decrease in trade and other receivables	33,170	67,871	9,729
(Decrease)/increase in trade and other payables	(214,810)	(28,529)	66,321
Cash generated from operations	(1,508,259)	(1,459,794)	(2,763,460)
Income taxes received	250,965	124,714	124,713
Net cash from operating activities	(1,257,294)	(1,335,080)	(2,638,747)
Cash flows from investing activities			
Asset acquisition	-	-	-
Grant monies	9,776	5,556	64,668
Other income		49,725	49,725
Finance income	2,235	15,617	17,121
Net cash used by investing activities	12,011	70,898	131.514
Net increase/(decrease) in cash and cash equivalents	(1,245,283)	(1,264,182)	(2,507,233)
Cash and cash equivalents at beginning of the year	3,059,001	5,566,234	5,566,234
Cash and cash equivalents at end of the period	1,813,718	4,302,052	3,059,001

Scancell Holdings plc
Notes to the Interim Financial Statements
for the period to 31 October 2015

1 Basis of preparation

This interim statement for the six month period to 31 October 2015 is unaudited and was approved by the Directors on 26 January 2016. The financial information contained in the interim report has been prepared in accordance with the accounting policies set out in the annual report and accounts for the year ended 30 April 2015.

The financial information contained in the interim report does not constitute statutory accounts as defined in section 434 of the Companies Act 2006. The financial information for the full preceding year is based on the statutory accounts for the year ended 30 April 2015, upon which the auditors, Champion Accountants LLP, issued an unqualified audit opinion which did not contain any statement under section 498(2) or 498(3) of the Companies Act 2006. The audited statutory accounts for the year ended 30 April 2015 have been lodged with the Registrar of Companies.

As permitted, this interim report has been prepared in accordance with AIM Rule 18 and not in accordance with IAS 34 “Interim Financial Reporting” therefore it is not fully in compliance with IFRS as adopted by the European Union.

2 Earnings per share

Basic earnings per share, from continuing operations, is calculated by dividing the earnings attributable to ordinary shareholders by the weighted average number of ordinary shares outstanding during the year.

The calculations of earnings per share are based on the following losses and numbers of shares.

	Six months to 31/10/2015	Six months to 31/10/2014	Year ended 30/04/2015
Loss after taxation	(1,174,963)	(1,339,915)	(2,414,630)
Weighted average number of shares	224,950,683	224,950,683	224,950,683
Basic earnings per share	(0.52)p	(0.60)p	(1.07)p

At 31 October 2015 the Company had 224,950,683 Ordinary Shares of 0.1p in issue.

3 Taxation

Taxation for the six months ended 31 October 2015 is based on the effective rates of taxation which are estimated to apply for the year ended 30 April 2016.

4 Interim results

These results were approved by the Board of Directors on 26 January 2016. Copies of the interim report are available to the public from the Group’s registered office and the Group’s website, www.scancell.co.uk.